



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/977,074 | 10/12/2001 | Richard Boyd | 156857-0042 | 1931 |

29000 7590 12/31/2002

IRELL & MANELLA LLP
1800 AVENUE OF THE STARS
SUITE 900
LOS ANGELES, CA 90067

EXAMINER

BELYAVSKYI, MICHAEL A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 12/31/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/977,074 | BOYD, RICHARD | |
| | Examiner | Art Unit | |
| | Michail A Belyavskiy | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37 are pending.

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-2 and 12-18 drawn to a method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein the method of disrupting sex steroid mediated signaling to the thymus is through surgical castration, comprising the step of monitoring the concentration of one or more thymopoietic cytokines, classified in classified Class 119, subclass 174; Class 435, subclasses 7.1.
 - II. Claims 1 and 3 -18, drawn to a method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein the method of disrupting sex steroid mediated signaling to the thymus is through administration of pharmaceuticals comprising the step of monitoring the concentration of one or more thymopoietic cytokines , classified in Class 424, subclasses 184.1; Class 435, subclasses 7.1.
 - III. Claims 1-2 and 19-25 drawn to a method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein the method of disrupting sex steroid mediated signaling to the thymus is through surgical castration, comprising the step of monitoring the concentration of one or more thymopoietic hormones, classified in classified Class 119, subclass 174; Class 435, subclasses 7.1.
 - IV. Claims 1, 3 -11 and 19-25, drawn to a method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein the method of disrupting sex steroid mediated signaling to the thymus is through administration of pharmaceuticals comprising the step of monitoring the concentration of one or more thymopoietic hormones, classified in Class 424, subclasses 184.1; Class 435, subclasses 7.1.

Art Unit: 1644

- V. Claims 26-28, drawn to a method for identifying thymic factors, classified in Class 435, subclasses 69.6.
- VI. Claims 1-2 and 29-37 drawn to a method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein the method of disrupting sex steroid mediated signaling to the thymus is through surgical castration, comprising the step of monitoring the production of new T cells, classified Class 119, subclass 174; Class 435, subclasses 325.
- VII. Claims 1, 3 -11 and 29-37, drawn to a method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein the method of disrupting sex steroid mediated signaling to the thymus is through administration of pharmaceuticals comprising the step of monitoring the production of new T cells, classified in Class 424, subclasses 184.1; Class 435, subclasses 325.

2. Groups I - VII are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

4. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

Art Unit: 1644

5. If Group II, or IV, or VII is elected, applicant is required to elect a specific method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein specific pharmaceutical is, for example, selected from the Groups recited in Claim 6.

These species are distinct because the method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, wherein specific pharmaceutical is, for example, selected from the Group recited in Claim 6 differ with respect to the use of specific pharmaceutical; thus each specific method employing a specific pharmaceutical represents patentably distinct subject matter. Furthermore, the examination of specific pharmaceutical such as ones recited in the Claims 6, in the method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling would require different searches in the scientific literature.

In addition to selecting specific pharmaceutical,

6. If Group III or IV is elected, applicant is required to elect a specific method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, comprising the step of monitoring the concentration of specific thymopoietic hormone wherein specific thymopoietic hormone is selected from the Groups recited in Claim 20.

These species are distinct because the method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, comprising the step of monitoring the concentration of specific thymopoietic hormone wherein specific thymopoietic hormone is selected from the Groups recited in Claim 20 differ with respect to the use of specific thymopoietic hormone; thus each specific method employing a specific thymopoietic hormone represents patentably distinct subject matter. Furthermore, the examination of specific thymopoietic hormone such as ones recited in the Claims 20 in the method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling would require different searches in the scientific literature.

7. If Group VI or VII is elected, applicant is required to elect a specific method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling, comprising the step of monitoring the production of new T cells wherein specific PCR primer is selected from the Groups recited in Claim 32.

These species are distinct because the method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling comprising the step of monitoring the production of new T cells, wherein specific PCR primer is selected from the group recited in claim 32, differ with respect to the use of specific PCR primer; thus each specific method employing a specific PCR primer represents patentably distinct subject matter. Furthermore, the examination of specific PCR primer recited in the Claim 32 in the method for determining susceptibility of a thymus in a patient to activation through disruption of sex steroid signaling would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

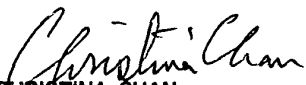
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
December 30, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600